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10/601,912

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Richard L. Antrim

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FITCH, EVEN, TABIN & FLANNERY
120 SOUTH LASALLE STREET
SUITE 1600
CHICAGO, IL 60603-3406

EXAMINER

BLAND, LAYLA D

ART UNIT

PAPER NUMBER

1623

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/601,912 | Applicant(s) ANTRIM ET AL. | |
| | Examiner LAYLA BLAND | Art Unit 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,34,35 and 41-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,34,35 and 41-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 30, 2009 has been entered.

This Office Action is in response to Applicant's request for continued examination (RCE) filed on April 30, 2009, and amendment and response to the Final Office Action (mailed January 30, 2009), filed on April 30, 2009 wherein claim 1 is amended, claims 5-33 and 36-40 are canceled, and claims 41-43 are newly submitted.

Claims 1, 2, 34, 35, and 41-43 are pending and are examined on the merits herein.

In view of the cancellation of claims 36, 39, and 40, all rejections made with respect to those claims in the previous office action are withdrawn.

In view of Applicant's amendment submitted April 30, 2009, the rejection of claims 1, 2, 4, 34-36, 39, and 40 under 35 USC 112, second paragraph, for indefiniteness with respect to "substantially digestible by mammalian enzymes" is withdrawn.

In view of Applicant's amendment submitted April 30, 2008, the rejection of claims 1, 2, 4, 34, and 35 under 35 U.S.C. 102(b) as being anticipated by Yoshida is

withdrawn. The amended claims require the presence of 1,2 and 1,3-bonds, which is not taught by Yoshida.

Claim Objections

Claim 43 is objected to because of the following informalities: the claim lacks a period at the end. Appropriate correction is required.

The following are new rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 34, 35, and 41-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and dependent claims 2, 4, 34, 35, and 41-43 recite the limitation "said mixture comprising a starch hydrolyzate to which additional saccharide has been added." Claim 1 refers to two mixtures: a "saccharide-derivatized oligosaccharide mixture," which is the product of an extrusion reaction, and "a mixture of malto-oligosaccharides," which is a starting material in the extrusion reaction. It is unclear which of these mixtures comprises the starch hydrolyzate to which additional saccharide has been added, and thus whether the starch hydrolyzate to which additional

saccharide has been added was part of the reaction mixture or might have been added after the reaction.

Claim 2 recites the limitation "a mixture according to claim 1." Claim 1 recites two mixtures, as mentioned above. It is unclear whether the mixture of claim 2 refers to the saccharide-derivatized oligosaccharide mixture (the product) or the mixture of malto-oligosaccharides (starting material), because the product can contain malto-oligosaccharides other than those in the "mixture of malto-oligosaccharides," such as the "additional saccharide" or oligosaccharides created during the reaction.

Claim 34 depends from claim 1 and recites the limitation "a portion of said saccharide." Claim 1 recites a "saccharide product" and an "additional saccharide." Furthermore, all of the starting materials and the product of claim 1 are saccharides. It is unclear which of these is intended in claim 34.

Claim 41 depends from claim 1 and recites the limitation "said saccharide." This is indefinite for the reasons given above for claim 34.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 34, 35, 41, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Saleeb (US 5,972,395, October 25, 1999) as evidenced by Tate & Lyle (Maltodextrins & Corn Syrup Solids).

Saleeb teaches a product prepared by extruding a mixture of glucose, maltose, maltotriose, mannose, sugar alcohols, adipic acid, citric acid, or malic acid, or a combination thereof; and high maltose corn syrup solids and/or 5-20 DE maltodextrin. The extrusion may be carried out at temperatures up to 190°C. [claims 1-10]. As evidenced by Tate & Lyle, 5 DE maltodextrin contains dextrose (about 1%) along with other oligosaccharides, 88% of which are DP11+ or higher. Thus, citric acid along with dextrose and other malto-oligosaccharides which are starch hydrolysates and have DP of 5 or more were extruded. The “additional saccharide” could be any of the oligosaccharides present in the mixture. Although Saleeb does not teach whether the product contains a majority of 1,4-bonds as well as some 1,2- and 1,3-bonds, the product is made by the same process as is recited in the instant claims, so the product should be the same as that of the instant claims. Thus, the claims are anticipated.

Claims 1, 2, 4, 34, and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Porzio (US 5,603,971, February 18, 1997) as evidenced by Tate & Lyle (Maltodextrins & Corn Syrup Solids).

Porzio teaches a process wherein 10 DE maltodextrin, 42 DE corn syrup solids, and 0.5 wt% citric acid were extruded at 300°F (about 149°C). Typically, the temperature will be up to 320°F (about 160°C). The maltodextrin and corn syrup solids

(starch hydrolyzates) comprise a variety of oligosaccharides, including dextrose and those which have DP of 5 or greater, as evidenced by Tate & Lyle. The “additional saccharide” could be any of the oligosaccharides present in the mixture. Although Porzio does not teach whether the product contains a majority of 1,4-bonds as well as some 1,2- and 1,3-bonds, the product is made by the same process as is recited in the instant claims, and so the product should be the same as that of the instant claims. Thus, the claims are anticipated.

The following rejections of record are maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 34, 35, and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Okhuma (US 5,358,729, October 25, 1994, of record).

Okhuma teach a product which was prepared by extrusion of corn starch in the presence of hydrochloric acid [column 14, Experimental Example 1]. Characteristics of the products prepared are shown in Table 4. Sample No. 1, for example, contains 53.6% of 1,4-bonds and also contains 1,3- and 1,2-bonds. A different product had 62.3% of 1,4-bonds, as well as 1,2- and 1,3-bonds [Table 7, first entry]. Limitations regarding how the extrusion reaction is performed, such as internal sample

temperature, do not add patentable weight to the claims. Thus, the claims are anticipated.

Response to Arguments

Applicant argues that Okhuma does not use a starch hydrolyzate or a product including 50% dextrose as the starting material, and that Okhuma does not suggest addition of "additional" saccharide to the hydrolyzed starch. This argument is not persuasive because the claims are drawn to a product prepared by extrusion of various saccharides, not the method of preparing it. Okhuma's product is a mixture of dextrans and contains the linkages as recited in claim 1. Thus, Okhuma's product appears to be the same as one prepared by the process recited in claim 1. The extrusion reaction is expected to result in bond breakage (starch hydrolysis) and new bond formation, and it is unclear how the addition of dextrose, as recited in amended claim 1, would affect the structure of the final product. Applicant mentions only that the dextrose serves as a processing aid. Furthermore, it is noted that no particular amount of dextrose or saccharide product is required by the claims. Thus, the claims are seen to encompass products prepared by the extrusion of mixtures which contain very small amounts of dextrose. Even if the effect of dextrose on the structure of the final product was clear, products prepared with very small amounts of dextrose would be very difficult to distinguish from Okhuma's product, since hydrolysis of starch and thus liberation of small oligosaccharides very likely occurs during Okhuma's process.

Applicant argues that Okhuma teaches away from products having a majority of 1,4 bonds. This argument is not persuasive because Okhuma explicitly teaches such as product, as set forth above.

Claims 1, 2, 4, 34-35, and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyers (US Patent 5,518,739, of record).

Meyers teaches Fibersol, a maltodextrin derivatized with dextrin via glycosidic linkages such as α -1,6, β -1,2, β -1,3 and β -1,6 (col.3, lines 22-24). As recognized by Applicant in the declaration of Dr. Mungara submitted August 7, 2007 and in the response submitted November 14, 2008, Fibersol has 51.5% of 1,4-bonds and is digested by mammalian enzymes more slowly than glucose. Limitations regarding how the extrusion reaction is performed, such as internal sample temperature, do not add patentable weight to the claims. Thus, the claims are anticipated.

Response to Arguments

Applicant argues that Fibersol is an indigestible product and is different from the product claimed in the present application. This argument is not persuasive because the process conditions are broad and do not exclude formation of an indigestible product. The instant specification (page 11) states that the instant products may be substantially inert to digestion by mammalian enzymes. Furthermore, products prepared by the process recited in claim 1 have widely varying digestibilities, which can be as low as about 5%.

Applicant argues that the Mungara declaration does not report a majority of 1,4 bonds in Fibersol. Applicant states that the table on page 8 of the most recent response shows a value of 51.5% 1,4 bonds if the Mungara data were represented in the form shown in the Fouache reference, but this representation is not the same as the expressed in the Mungara declaration. It is unclear how the limitation “majority of the linking bonds are 1,4-bonds” is to be interpreted if the representation shown in the Fouache reference and on page 8 of Applicant’s response is not acceptable. It is noted that, unless the data is presented as on page 8 of Applicant’s response, even Applicant's examples presented in the Mungara declaration do not have a majority of 1,4-bonds. Thus, Fibersol is considered to have 51.5% of 1,4-bonds, which is a majority.

For these reasons, the rejection is maintained.

Claims 1, 2, 4, 34-34, and 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Fouache et al. (US Patent 6,630,586, of record).

Fouache et al. disclose maltodextrin derivatized with dextrin via glycosidic linkages such as α -1,6 and α -1,4 (claim 1). Fouache et al also disclose maltodextrin derivatized with dextrin via glycosidic linkages such as 1-2, 1-3, 1-4, and 1-6 (Co1.8, Tables I and II). Products having 50% or 95% of 1,4-linkages are exemplified [column 8, Table I]. The product having 50% of 1,4-linkages also had 10% each of 1,2- and 1,3-linkages. As discussed above, it is not clear whether “extrusion” will necessarily result in a product having 1,2- and 1,3-bonds and thus claims 1, 2, 4, 34, and 35 are

anticipated by products D and E of Table I, which have 95% 1,4-bonds. Product C is disclosed by Fouche et al. as having 50% 1,4-linkages. Applicant's response submitted November 14, 2008 indicates that the percentage of 1,4-bonds in the Nutriose product was experimentally determined to be 49.6% by Dr. Mungara, when multiple linkages are counted. Using the declaration of Dr. Mungara submitted August 7, 2007 (Table 2), the examiner added the percentages for all the 4-glc values for Nutriose, including the multiple linkages. 4-glc was indicated on page 4 of the declaration to be where a branch point existed at the 4-position. The result of that calculation was 55.7%, which is a majority. Thus, the claims are anticipated.

Response to Arguments

Applicant argues that Nutriose does not contain a majority of 1,4-bonds, and states that if the data contained within the declaration of Dr. Mungara submitted August 7, 2007 is recalculated, the percent of 1,4-bonds in Nutriose is 49.6%. It is unclear how the calculation was performed. The declaration of Dr. Mungara states that, for instance, "3,4-glc" indicates where a branch point had existed at the 3- and 4- position. The examiner understands that to mean that there is a 1,4-linkage on that particular position. It is unclear why these are not 1,4-bonds or why these require a separate calculation. Because Applicant's argument is not clear, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 34, 35, and 41-43 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stahl (WO 01/33973, May 17, 2001, human translation, of record).

Stahl teaches a modified carbohydrate made of a base body and a carbohydrate residue coupled therewith [abstract]. In example 1, maltodextrin was derivatized with glucose residues [pages 19-21 of human translation document]. Products obtained by derivatization of maltodextrin with glucose in the 1-2, 1-3, 1-4, or 1-6 position are specifically claimed [claim 4], and are preferably obtained by the use of transglucosidase from *Leuconostoc mesenteroides* [claim 5].

Stahl does not teach the percentage of bonds which are 1,2-, 1,3-, 1,4-, or 1,6-bonds. However, since Stahl's product is a derivatized maltodextrin, which is has 1,4-bonds, and because Stahl et al. teaches that the product of Example 1A is digestible [claim 1 and Figure on page 31], the skilled artisan would expect that Stahl's product contains a majority of 1,4-bonds. Further, Stahl provides guidance for the desirable characteristics of the product, glucose release [claim 1], and provides guidance for the use of other enzymes [page 17 and 18], and for variation of process conditions [page

19-25]. Thus, the skilled artisan would have motivation and guidance to optimize process conditions to obtain a product with moderated glucose release.

Response to Arguments

Applicant argues that the claimed product has different types of bonds and a different distribution of linkages than Stahl's product. This argument is not persuasive because the process conditions are so broad that it is not clear whether the process will necessarily result in a product having linkages or assortment of bonds which is substantially different from Stahl's product. The specification, page 11, states that "it is believed that relatively low levels of chemical modification of the starting material will produce a product having some non 1-4 linking bonds, (e.g. 1-2, 1-3, or 1-6 bonds)." It is noted that Stahl teaches a product having these bonds. The specification, page 10, also states that the extruder can be any conveying device in which temperature, vacuum, water, and starting materials can be introduced with adequate mixing to result in derivatization, and that barrel temperatures can be as low as 25°C. Because the recited process conditions are so broad, and because it is unclear from the specification which particular conditions are required to produce types and assortments of bonds, Applicant's argument is not persuasive.

Applicant argues that Stahl's product is specific and well-defined, unlike the claimed product which has randomly produced bonds of several types. This argument is not persuasive because the claims require a product which has a majority of 1,4-bonds and also contains 1,2- and 1,3-bonds. Stahl's product meets those limitations, as discussed above. The instant claims do not require any distribution of bonds other than

a majority of 1,4 bonds, which Stahl's product likely meets, as set forth above. Thus, the rejection is maintained.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623